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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,414	03/18/2004	Valerie Niddam-Hildesheim	1662/55205	5552
26646	7590	11/01/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,414

Applicant(s)

NIDDAM-HILDESHEIM ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 43-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 43-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-44 are rejected under 35 U.S.C. 102(b) as being anticipate by Hirai et al., US 5,260,440.

Hirai et al., disclose compositions of rosuvastatin calcium salt comprising the salt and pharmaceutically acceptable excipients. See columns 2-10, example 1 and claims 1,4. The instant invention is drawn as a product-by process claim. However, patentability of product-by-process claim is based on the product itself. Though, the claims are limited and defined by their process of making, the products are unpatentable if they are the same or obvious from the product of a prior art. *In re Thorpe*, 227 USPQ 964 (CAFC, 1985). See also *Ex parte Gray*, 10 USPQ 2d 1922.

Claims 43, 45 are rejected under 35 U.S.C. 102(b) as being anticipate by Fujikawa et al., US 5,011,930.

Fujikawa et al., disclose compositions of pitavastatin calcium salt comprising the salt and pharmaceutically acceptable excipients. See columns 2-11, the tables and the claims. The instant invention is drawn as a product-by process claim. However, patentability of product-by-process claim is based on the product itself. Though, the claims are limited and defined by their process of making, the products are

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unpatentable if they are the same or obvious from the product of a prior art. *In re Thorpe*, 227 USPQ 964 (CAFC, 1985). See also *Ex parte Gray*, 10 USPQ 2d 1922.

Claims 43, 46 are rejected under 35 U.S.C. 102(b) as being anticipate by Hoffman et al., US 4,444,784.

Hoffman et al., disclose compositions of simvastatin calcium salt comprising the salt and pharmaceutically acceptable excipients. See column 15; example 6, compound 1; and claims 1-4,6-9. The instant invention is drawn as a product-by process claim. However, patentability of product-by-process claim is based on the product itself. Though, the claims are limited and defined by their process of making, the products are unpatentable if they are the same or obvious from the product of a prior art. *In re Thorpe*, 227 USPQ 964 (CAFC, 1985). See also *Ex parte Gray*, 10 USPQ 2d 1922.

Claims 43, 47 are rejected under 35 U.S.C. 102(b) as being anticipate by Roth, US 4,681,893.

Roth discloses compositions of atorvastatin calcium salt comprising the salt and pharmaceutically acceptable excipients. See columns 2-8; example in step G, column 12, example 2, column 14; and claims 1, 8. The instant invention is drawn as a product-by process claim. However, patentability of product-by-process claim is based on the product itself. Though, the claims are limited and defined by their process of making, the products are unpatentable if they are the same or obvious from the product of a

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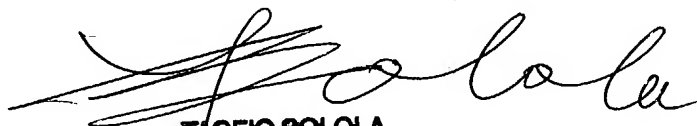
prior art. *In re Thorpe*, 227 USPQ 964 (CAFC, 1985). See also *Ex parte Gray*, 10 USPQ 2d 1922.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Taofiq Solola', with a stylized flourish at the end.

**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1626

October 25, 2004